

**caBIG Strategic Planning Working Group
Face-to-Face Meeting Notes
Philadelphia, PA
November 8 – 9, 2004**

The caBIG Strategic Planning Strategic Level Working Group held its first face-to-face meeting November 8-9, 2004 in Philadelphia, PA. The meeting was hosted by Fox Chase Cancer Center. Bob Beck served as moderator.

Attendees, agenda, meeting discussions and outcomes follow.

Attendees:

Mark Adams, Booz Allen Hamilton
Mike Becich, University of Pittsburgh
J. Robert Beck, Fox Chase
Howard Bilofsky, University of Pennsylvania
David Birtwell, University of Pennsylvania
Jessica Bondy, University of Colorado
Ken Buetow, NCICB
John Casagrande, University of Southern California
Thomas Casavant, University of Iowa
Amin Chisti, Fox Chase
John Cook, MD Anderson
Peter Covitz, NCICB
Chalk Dawson, Booz Allen Hamilton
Mary Jo Deering, NCICB
Leslie Derr, NCICB
David Fenstermacher, University of Pennsylvania

Dan Geraghty, Fred Hutchinson
William Grizzle, University of Alabama at Birmingham
Kim Johnson, Duke University
Michael Keller, Booz Allen Hamilton
Arumani Manisundaram, Booz Allen Hamilton
Frank Manion, Fox Chase
Joyce Niland, City of Hope
Michael Ochs, Fox Chase
Bob Robbins, Fred Hutchinson
Lincoln Stein, Cold Spring Harbor
David Stivers, MD Anderson
R. Michael Townsend, Cold Spring Harbor
David Tuck, Yale University
Mark Watson, Washington University
Theodora Wills, Booz Allen Hamilton

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AGENDA

<i>Day 1: Monday, November 8, 2004</i>	
7:15 am	Bus departs Penn's View Hotel for Fox Chase Cancer Center
8:00 am – 8:30 am	Breakfast – Fox Chase Conference Rooms C&D
8:30 am – 8:45 am	<p style="text-align: center;">Welcome <i>Anna Marie Skalka, Senior Vice President for Basic Sciences, FCCC</i> <i>R. Donald Leedy, Executive Vice President/Chief Operating Officer, FCCC</i></p>
8:45 am – 9:15 am	<p style="text-align: center;">Purpose and Goals <i>Ken Buetow, Director, NCI</i> <i>Bob Beck, FCCC, Meeting Moderator</i></p>
9:15 am - 10:00 am	<p style="text-align: center;">Clinical Trials Management Systems Workspace <i>Facilitator: Joyce Niland – City of Hope</i></p>
10:00 am –10:15 am	BREAK
10:15 am – 11:00 am	<p style="text-align: center;">Integrative Cancer Research Workspace <i>Facilitator: Tom Casavant – University of Iowa</i></p>
11:00 am –11:45 pm	<p style="text-align: center;">Tissue Bank and Pathology Tools Workspace <i>Facilitator: William Grizzle – University of Alabama - Birmingham;</i> <i>Mark Watson – Washington University</i></p>
11: 45 am - 12:30 pm	<p style="text-align: center;">Architecture Workspace <i>Facilitators: Bob Robbins – Fred Hutchinson; Mike Ochs – FCCC</i></p>
12:30 pm – 1:30 pm	LUNCH
1:30 pm – 2:15 pm	<p style="text-align: center;">Vocabularies and Common Data Elements Workspace <i>Facilitator: Mike Becich – University of Pittsburgh</i></p>

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2:15 pm – 3:00 pm	Data Sharing and Intellectual Capital Working Group <i>Facilitator: Mark Watson – Washington University</i>
3:00 pm – 3:15 pm	B R E A K
3:15 pm – 4:00 pm	Training Working Group <i>Facilitator: Leslie Derr, NCI; Mark Adams, Booz Allen Hamilton</i>
4:00 pm – 5:00 pm	DISCUSSION
5:00 pm – 5:15 pm	Wrap-up/Discussion of tomorrow's agenda items
5:15 pm	Bus leaves for Penn's View Hotel
6:30 pm	Reception and Dinner Ristorante Panorama – Penn's View Hotel
Day 2: Tuesday, November 9, 2004	
7:30 am – 8:00 am	Breakfast – Penn's View Hotel
8:00 am – 10:00 am	Open Discussion <i>Cross cutting Issues</i> <i>Connections</i>
10:00 am – 10:15 am	B R E A K
10:15 am – 12:00 pm	Preliminary work on overarching caBIG 3 yr and 5 yr goals
12:00 pm – 1:00 pm	L U N C H
1:00 pm – 3:00 pm	Assignments in preparation for March 15-16, 2005 face-to-face meeting
3:00 pm	A D J O U R N

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I. caBIG Goals

caBIG Strategic Goals

1 year (end of 2005)	3 year (Summer 2008)	5 year (Summer 2010)
<ul style="list-style-type: none"> Develop first generation caBIG compliant tools and data sets and supporting data & architecture standards Establish a mechanism for engaging the private sector (pharma, SW Vendors, etc.), additional cancer research organizations, and other Federal agencies/divisions 	<ul style="list-style-type: none"> caBIG will have sufficient mass of tools & data sets to have a positive impact on the cancer research community All Developer projects will be operating under Gold standard Adoption and use of caBIG interoperable tools and data sets within the caBIG Community Develop mechanisms for engaging and promoting the use of these technologies and data sets for not just research but to include clinical treatment activities 	<ul style="list-style-type: none"> Wide spread adoption, dissemination and use of caBIG interoperable tools and data sets within the Cancer Community at large including pharma, non-NCI Cancer Centers, etc.
Guiding Principles <ul style="list-style-type: none"> All software products must be optimized for change rather than trying to get it perfect the first time out. The ability to easily adapt our software products to future changes and external influences is essential. We must have a bias for action, and not get bogged down in deliberating everything to the nth detail Always retain a patient centric focus in conceptualizing and developing our solutions 		

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II. WORKSPACE and WORKING GROUP OBJECTIVES

Clinical Trial Management Systems (CTMS)

SIG	1 year	3 year	5 year
Financial Billing	<p>While focusing on the Trial Financial Ledger,</p> <ul style="list-style-type: none"> • Drill down further into the Use Cases • Create list of the data elements flowing between study calendar and the financial entity at the Cancer Center • Create a glossary defining financial terms • Describe interactions among components of the model • Describe the functional requirements of each component • Develop functional requirement and specification documents • Develop Statement of Work (SOW) 	<p>Execute SOW:</p> <ul style="list-style-type: none"> • Develop risk management plans • Load CDEs into ISO11179-compliant metadata repository • Create a test approach for ‘white box’ testing • Implement software features • Execute testing approach • Create User Documentation and installation guides • Create training plan • Deploy software to adopter sites and train sites 	
Laboratory Interfaces	<ul style="list-style-type: none"> • Identify any needed CDISC modifications, and work with 	<ul style="list-style-type: none"> • caBIG lab module should be successfully transferring lab 	<ul style="list-style-type: none"> • caBIG lab module should be supplying de-identified lab

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	<p>CDISC to make them</p> <ul style="list-style-type: none"> Understand from vendors what is needed to collaborate on HL7 v3 interface for transmitting CT lab messages Formulate plan for cooperation with Adverse Event (AE) workspace on supplying key lab data for AE reporting 	<p>data from at least 2 major clinical lab systems, allowing customizable filtering of data into the CTMS</p> <ul style="list-style-type: none"> The Cancer Centers should have a means of automatic transfer of lab data into clinical trials databases without re-keying data 	<p>data to the grid</p> <ul style="list-style-type: none"> A toolkit should be available to facilitate development of an interface for data transfer from any clinical laboratory system
Adverse Event	<ul style="list-style-type: none"> Functional prototype for Modules 1-4 of AE Reporting system developed in caBIG compatible fashion and tested at adopter sites 	<ul style="list-style-type: none"> All 12 modules operational and in place at Cancer Centers, with interfaces to legacy/vendor systems, and single rules engine for electronic internal routing and external reporting to various entities 	
CDUS/CTMS Reporting	<ul style="list-style-type: none"> Determine and thoroughly document CDUS/CTMS issues and needs via Use Cases Make incremental improvements to facilitate the reporting process with CTEP 	<ul style="list-style-type: none"> Create caBIG-compatible software module to encompass current CDUS/CTME reporting requirements Work with AE SIG and City of Hope to establish the denominator for mining for previously undetected patterns within an AE Data Warehouse nationwide 	
caBIG Compatibility	<ul style="list-style-type: none"> Along with cross-cutting work spaces, deliver a refined caBIG compatibility guideline document that is proven to 		

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	<p>facilitate analysis of current and emerging software systems in this regard</p> <ul style="list-style-type: none"> • Determine methods for assessing whether suggestions for revision encompass needs and direction of the caBIG Architecture, Vocabulary and Strategic Planning groups • Summarization of the ‘gap analysis’ for guidelines against future needs 		
Structured Protocol Representation	<ul style="list-style-type: none"> • Identify appropriate level of granularity for protocol representation • Determine functional requirements for effective protocol representation • Document requirements for caBIG-compatible tools for effective protocol representation • Develop a component of the specified module • Plan and pilot deployment of the selected component • Perform a detailed interoperability assessment of the specified module, with particular attention to the selected component 		

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Challenges
<ul style="list-style-type: none"> • For Adverse Event Reporting– <ul style="list-style-type: none"> ○ Open source software development ○ Soliciting and considering nationwide input ○ Incorporating national/international standards ○ Interfacing with in-house and vendor-based systems ○ Including both Cancer Centers & agency perspectives • Role of interactions with Oracle, other vendors • Lab interfaces and DSIC coordination

Integrative Cancer Research (ICR)

1 year	3 year	5 year
<ul style="list-style-type: none"> • The majority of projects will target Silver Level compliance, as outlined in the caBIG Compatibility Guidelines document. A few projects will be selected as reference implementations of the Grid architecture. All projects will comply with the caBIG principles of open source, open access, open development and federation 	<ul style="list-style-type: none"> • Bring more selected data sources and applications into Gold-level compliance, i.e. make them grid resources. • Show how a federated set of resources that are syntactically and semantically compatible can be used to perform powerful analyses across the cancer research community. 	<ul style="list-style-type: none"> • Connect the ICR data and applications to resources in the Tissue Banks and Pathology Tools Workspace as well as the Clinical Trials Management System Workspace
Challenges		
<ul style="list-style-type: none"> • “Tightening” the group – how do projects “fit” together? • “Cementing” the Developer-Adopter relationships (More use-cases need to be developed jointly) • Increasing awareness crossing... <ul style="list-style-type: none"> ○ Workspaces (beyond liaisons) ○ SIGs (distinction?/commonality?) 		

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<ul style="list-style-type: none"> • Uniform training • Uniform adoption of caBIG Architecture, CDEs and practices • Balancing Software Engineering with Science <ul style="list-style-type: none"> ○ Discussions ○ Effort • A “Vision” for the “Grid” • Remain cognizant of overlaps with CTMS and TBPT 		
SIG	Projects	Due Date
Data Analysis & Statistical Tools	Distance-Weighted Discrimination	<ul style="list-style-type: none"> • Q2 05: Beta version of caBIG-compatible DWD • Q4 05: Final caBIG-compatible DWD
	Gene Pattern	<ul style="list-style-type: none"> • Awaiting signing of BA at MIT
	Magellan	<ul style="list-style-type: none"> • Q2 05: Beta version of caBIO-interoperable Magellan • Q3 05: Final version of caBIO-interoperable Magellan; Beta version of caArray-interoperable Magellan • Q4 05: Final software
	VISDA	<ul style="list-style-type: none"> • Q2 05: Initial version of caBIG-VISDA • Q4 05: Final version of caBIG-VISDA
Genome Annotation	Cancer Molecular Pages	<ul style="list-style-type: none"> • Q3 05: Prototype version of Cancer Molecular Pages
	Function Express	<ul style="list-style-type: none"> • Q3 05: Beta version of caBIG-compatible FunctionExpress • Q4 05: Final version of caBIG-compatible FunctionExpress
	GoMiner	<ul style="list-style-type: none"> • Q1 05: Preliminary caBIG-compliant GoMiner • Q2 05: GoMiner with web-services API

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	HapMap	<ul style="list-style-type: none"> • Early Q3 05: Initial mapping of HapMap and Promoter DB to augmented caBIO • Late Q3 05: Final code available for loading HapMap and PromoterDB to augmented caBIO
	PIR	<ul style="list-style-type: none"> • Q2 05: PIR/Uniprot with middleware layer and web-services API
	SEED	<ul style="list-style-type: none"> • Tasks and deliverables under negotiation with cancer center
Microarray Repositories	CaArray	<ul style="list-style-type: none"> • Developed by NCICB – pure adoption activity
	NCI-60 Data Sharing	<ul style="list-style-type: none"> • "Q1 05: NCI-60 Affymetrix data available in caArray • Q2 05: NCI-60 drug screen data available in MAGE-ML tox format • Q2 05: NCI-60 cDNA Array data available in caArra; • Q3 05: NCI-60 karyotyping data available as SKYWEB files • NCI-60 aCGH data available in caArray"
	Zebrafish Microarray Data Sharing	<ul style="list-style-type: none"> • Tasks and deliverables under negotiation with cancer center
Pathways	Cytoscape	<ul style="list-style-type: none"> • "Q3 05: View BioPAX data in cPath database through Cytoscape; • Q4 05: Final caBIG-compliant Pathways system, including ability to import data from caArray"

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	QPACA	<ul style="list-style-type: none"> • "Early Q3 05: Beta version of QPACA integrated with Magellan • Late Q3 05: Final version of QPACA integrated with Magellan • Q4 05: QPACA interoperable with caBIG's pathways exchange standard "
	Reactome	<ul style="list-style-type: none"> • Tasks and deliverables under negotiation with cancer center
Proteomics	LIMS	<ul style="list-style-type: none"> • Q4 05: Prototype Proteomics LIMS implemented
	Q5	<ul style="list-style-type: none"> • Tasks and deliverables under negotiation with cancer center
	RProteomics	<ul style="list-style-type: none"> • "Q2 05: JavaR bridge • Q2 05: R routines • Q3 05: Rproteomics grid services and client application"
Translational	TrAPSS	<ul style="list-style-type: none"> • Q3 05: caBIG-compatible TraPSS implemented

Tissue Bank and Pathology Tools (TBPT)

1 year	3 year	5 year
<ul style="list-style-type: none"> • Complete first iteration of caTISSUE Core / caTISSUE Lite and deploy to adopter sites for testing. • Complete caTIES module and deploy to adopter sites for testing. • Complete first phase of caTISSUE 	<ul style="list-style-type: none"> • Complete development cycle for caTISSUE Lite / caTISSUE Core • Complete and deploy presentation / grid layer for caTISSUE • Further development of clinical annotation module. 	<ul style="list-style-type: none"> • Execute test cases to demonstrate utility of grid-based query of specimen data across institutions and consequent sharing of biospecimen resources for novel, multi-institutional studies.

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clinical annotation module and deploy to adopter sites for testing.	<ul style="list-style-type: none"> • Development of ‘second party’ modules <ul style="list-style-type: none"> ○ Billing / shipping ○ Request ○ •Experimental annotation • Addition of other caTISSUE modules based on ranking in prioritization matrix. • Explore the integration with other specimen bank systems (e.g. EDRN, cooperative group banks, CHTN) with caTISSUE. 	
Challenges		
<ul style="list-style-type: none"> • Coordination with DSIC regarding HIPAA and IRB issues 		

Architecture (ARCH)

1 year	3 year	5 year
<ul style="list-style-type: none"> • Move interoperability framework into production projects • Release of Compatibility Document Version 2.0 defining Gold Compatibility • Set target dates/milestones for implementation of compatibility guidelines • Identifier subgroup to determine if LSID is sufficient to meet the needs of caBIG 	<ul style="list-style-type: none"> • Develop a caCORE Developer’s Tool Kit 	<ul style="list-style-type: none"> •

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<ul style="list-style-type: none"> • Workflow subgroup to evaluate workflow technologies and provide a white paper with recommendations for caBIG • Common Query language subgroup to recommend a common standardized query language across the grid • Design & Prototyping based on Domain Workspace Use Cases • Identify particular Domain Workspace projects to use as vehicles for testing implementation strategies • Evaluate RDF and XML as the format for metadata representation at runtime • Interact closely with Arch and VCDE WS to address all issues being raised in the Workspaces 		
Challenges		
<ul style="list-style-type: none"> • Messaging of Architecture decisions should be brought back to the domain workspaces • Potential Bottleneck – Will mentoring team be able to serve all Workspaces and meet SOW deliverable timelines 		

Vocabularies & Common Data Elements (VCDE)

1 year	3 year	5 year
<ul style="list-style-type: none"> • Plan for governance of new vocabulary and common data element content • Establish VCDE Mentoring Teams for domain workspace pilot projects 	<ul style="list-style-type: none"> • 	<ul style="list-style-type: none"> •

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<ul style="list-style-type: none"> • Recommendation of external data standards • Convene regular Face to Face Meetings of the VCDE Workspace and joint meetings with the Architecture Workspace to address caBIG cross cutting issues • Implement VCDE Workspace developer projects 		
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Challenges
<ul style="list-style-type: none"> • Can 7 Centers support CDE Development for 29 projects? Is VCDE Workspace appropriately resourced? • The need to identify adopters for the development project, specifically the projects where terminologies are being added to the core infrastructure. (mouse vocabs for example) • How can the Centers be effectively supported in the use of the caDSR tools? Current training is “abstract”. The Centers are asking for specific context based training • Not enough emphasis on clinical and translation • Potential Bottleneck – Will mentoring team be able to serve all Workspaces and meet SOW deliverable timelines

Data Sharing and Intellectual Capital (DSIC)

SIGs/Focus Groups

- Regulatory Focus Team – IRB, HIPAA, Privacy
- Proprietary - ownership
 - Experimental data
 - Application/code /licensing
 - Biospecimens & associated data

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1 year	3 year	5 year
<ul style="list-style-type: none"> Develop key data sharing associated use cases for each of the caBIG workspaces. Collect and compile existing “best practices” related to proprietary and regulatory issues for data sharing. Where no “best practices” exist, seek out needed expertise to formulate such policies for caBIG activities. Prepare position papers on assigned topics relevant to each team focus. 	<ul style="list-style-type: none"> Publish white papers (consensus documents) based on summation of group’s position papers. Continue interaction with Architecture WS to develop test documents Create caBIG compliant document templates that can be used by participating institutions to ensure compliances with data sharing policies 	<ul style="list-style-type: none"> Serve as liaison between policy changes and system design Troubleshoot remaining institutional impediments to implementing data sharing across the grid

Challenges

- How do we get the IRBs to support any approach we develop?
- Need for discussions around security

Training

1 year	3 year	5 year
<ul style="list-style-type: none"> Develop caCORE training (EVS,caDSR, caBIO) Develop Training for tools currently being developed starting with <ul style="list-style-type: none"> CTMS - Structured Protocol Development 	<ul style="list-style-type: none"> Provide an open source electronic learning environment Define Training Modalities Produce “Gold” level training materials 	

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<ul style="list-style-type: none"> ○ ICR – caARRAY ○ TBPT - caTIES • Develop templates & standards for caBIG Software Documentation • Develop common standards for the evaluation of caBIG tools 	<ul style="list-style-type: none"> • Provide a common look and feel for caBIG training materials • Provide end user & tech support 	
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Challenges
<ul style="list-style-type: none"> • Provide training on a caCORE in a timely fashion • Provide guidelines for software documentation • We could get space at APIII & BRIITE to provide caBIG training sessions per Mike Becich & Bob Robbins

III. Key Discussion Points and Decisions

New Potential Workspaces/Group to engage:

- Population Sciences
- ONCHIT/EMR/CHI – Federal/Regulatory
- Cancer Imaging Program
- ICBPO
- COOP, SPORES, CTEP
- Commercial Sector (Pharma, SW Vendors, etc.)
- Other Federal Agencies

Key Decisions:

- Meeting Notes
 - Need to distill the meeting minutes down to the most appropriate info; key decisions & action items
 - Communication mechanisms must become crisper and more focused.
 - Post notes as a WIKI and searchable page
- Approaches to Decision Making Process
 - Conduct quarterly teleconferences (audio and Centra) that are open to the entire caBIG community
 - Review all Workspace activities, goals, emerging issues and decisions
 - Identify and cement Workspace interfaces and interdependencies, e.g., security, business process, access management
 - Frame agenda so teleconference is no longer than 2 hours
 - Discuss what one group expects another to deliver
 - Review any changes to previously discussed plans

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- Create a ‘technical’ segment in What’s Big This Week to summarize Workspace products and teleconference notes
 - Use as a notification process of key decisions being made
 - Summarize teleconference notes and important topics
 - Link to papers out for comment
 - Incorporate good search engine on website including date parameters
 - Provide Executive Summary with links to web site to detailed information
- Key Decision Making Process
 - Identify a topic Lead
 - Topic Lead convenes 1-2 brainstorming sessions
 - Publicize when sessions will be held (What’s Big This Week; Listserv)
 - Develop proposal based on session feedback
 - Put proposal out for public comment across initiative for 1-2 wks
 - Topic Lead collects comments and makes final document
 - Publish final document
- Web site Changes
 - Post SIG and subcommittee contact information on web site
 - Post listing of projects under development and responsible Centers
 - Incorporate ‘technical’ section of What’s Big This Week

Big Questions:

- Do we have too many balls in the air? Should we be staging the activities over the next 3 years?
- What is our methodology for sequencing and managing our activities?
- What is the strategy for long-term user support? (similar to vendor support...goes beyond training) Should it be commercialized?
- Should some form of formal test bed be set or established to test and demonstrate architectural standards? (Should go back to Arch WS for discussion)
- How can the Centers be effectively supported in the use of the caDSR tools?? Current training is “abstract”. The centers are asking for specific context based training

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- How do we involve cooperative groups and other stakeholders?
- How do we envision commercial involvement?
- How do we maintain a patient centered focus/individualized medicine (including small oncology practices and nurses, EMR)
- Management of flexibility vs perfection tradeoff
- How should we be measuring the project's progress?
- How will we balance using resources for development vs support for existing products?

III. Next Steps

Action	Responsibility	Timeline
<ul style="list-style-type: none"> • Provide feedback from SP SLWG Face-to-Face meeting to the Workspaces. • Review 1, 3, and 5 year objectives for inconsistencies and confirm timeline for each objective. 	VCDE – Mike Becich CTMS – Joyce Niland TBPT – Mike Becich DSIC – Mark Watson ICR – Mike Ochs ARCH – Bob Robbins TRNG – Leslie Derr	Complete by respective Workspace's next teleconference
<ul style="list-style-type: none"> • Notify Workspace Leads to include facilitators on next Workspace teleconference 	Booz Allen	11/12/2004
<ul style="list-style-type: none"> • Compile and distribute (or post) face-to-face meeting notes, presentations and attendee list • Revise regular SP SLWG teleconference to a monthly cycle 	Booz Allen	11/12/2004
<ul style="list-style-type: none"> • Revamp What's Big This Week to include 'technical' update which provides high level summary of scheduled meeting across caBIG. 	Booz Allen	TBD
Lead development of position paper (700 words or less) for distribution to Center Directors and publication in science journals. Paper should discuss <ul style="list-style-type: none"> • caBIG goals and objectives 	Bob Beck	First Draft - 12/15/2004

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<ul style="list-style-type: none"> • what caBIG is and is not • where caBIG expects to be in one, three and five years • where and why Centers and community might want to get involved 		
<ul style="list-style-type: none"> • Finalize caBIG strategic goals and Workspace objectives. • Begin planning for March 15-16, 2005 SP SLWG Face-to-face meeting. (Identify host site and agenda) • Review status of position paper • Discuss methodology for managing and sequencing our activities 	SP SLWG Members	12/6/2004 (Next SP SLWG Teleconference)